Investigation of Hand-Arm Vibration (HAV) in Railroad Track Workers: Addressing Stakeholder Conflict of Interest

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Paul Landsbergis, School of Public Health, State University of New York, Brooklyn, NY
Background-Key Study Finding:

HEALTH AND SAFETY STUDY of MAINTENANCE-OF-WAY RAILROAD WORKERS

- die younger than the general population
- more likely to have cancer, lung problems, nerve diseases, early dementia, and significant joint pain.
- sick and injured MOW face serious financial challenges.
- Five diseases cost an estimated $2 billion dollars.

(From Executive Summary to BMWED, 2/2018)
Study

• The **Brotherhood of Maintenance-of-Way Employes Division (BMWED)** funded in 2014 three research teams:
  
  A. David Goldsmith, PhD, occupational epidemiologist, George Washington Uni., Wash. DC.
  
  B. Eckardt Johanning, MD, occupational medicine, Columbia University, New York, NY
  
  Paul Landsbergis, PhD, statistician/epidemiologist, SUNY Downstate, Brooklyn, NY
  
  C. Ruth Ruttenberg, PhD, economist, Rutgers University,

• **Objective:**
  
  ➢ to define the risks and impact of injury, illness, and mortality
  
  ➢ provide materials to educate members
  
  ➢ determine if there are empirical data …to mitigate conditions…through regulatory improvements and labor/management engagement

• **Method:**
  
  • Self-administered survey
  
  • Of 39000 members, 4800 respondents from 48 States, seven Class 1 railroads
Study design and methods

- BMWED facilitated contact to members, assured full confidentiality
- International research study team support
- **IRB** approval: Cook County Hospital (Chicago, Il.) and SUNY Downstate (Brooklyn, NY)
- National Institutes of Health (NIH) assurance: **Certificate of Confidentiality**
- Mailing survey (Engl./Spanish), option online completion, results recorded anonymously
- Selected worker interviews
- Follow-up of non-responder (written and phone)
- Survey questions(takes 45-60 minutes to complete):
  - demographics
  - use of vehicles, hand or power tools, work exposures,
  - symptoms, illnesses, and injuries,
    - Based on Nordic Musculoskeletal Questionnaire (NMQ),
    - Medical Research Council (MRC), National Survey of Health and Vibration in the UK,
    - European collaborative study of vibration related health risks (VIBRISKs))
  - social and economic impact of work-related injuries and illnesses
Results: Publications

Original study results: HAV issues

- MoW workers frequently reported typical hand-transmitted vibration-related Sx, and appeared to be at risk for neuro-musculoskeletal disorders of the upper extremity.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Active MoW men</th>
<th>U.S. employed men 18-74 yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>told by health provider they have carpal tunnel syndrome (CTS)</td>
<td>7.9%</td>
<td>3.6%</td>
</tr>
<tr>
<td>MOW: daily or weekly Sx during past year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>blanching when exposed to cold</td>
<td>143</td>
<td>3.7%</td>
</tr>
<tr>
<td>experienced white fingers (clearly demarcated)</td>
<td>77</td>
<td>2.0%</td>
</tr>
</tbody>
</table>
Time Line – Railroad Corp/AAR consultant approach

• 3/4/2020 Matt Thiese, University Utah email:
  “I was interested in your publication in JOEM from July investigating the overlap between those two areas of interest and I am writing to see if there is a possibility of obtaining the raw data to conduct additional analyses…” “I am both HIPAA and human subjects research certified.”

• 3/12/2020 Paul Landsbergis,
  • « We are still working on the analysis and manuscripts…, unable to share »
  • Who are « we » and for whom do you work?

• 10/15/2020 M Thiese letter:
Timeline continued:

- **10/16/2020 M Thiese, University Utah email:**
  “I apologize for not being clear in my earlier email. The “we” are myself, Dr. Kurt Hegmann, George Page and Greg Weames. We were asked by the Association of American Railroads to read your articles and provide our opinion.”

- **10/20/2020 P Landsbergis email to Thiese:**
  “we referred your request and emails to the BMWED for a reply. This organization owns and controls the data you keep requesting for obvious reasons.”

- **10/21/2020 Z.C. Voegel, BMWED lawyer reply:**
  - …strangely, your private letter was also copied to various Journal editors.
  - 2019 BMWED provided the full text of our Research Studies to the Association of American Railroads (AAR) and individual carriers …gone unanswered
  - ..disclosed “colleagues” including George Page and Greg Weames of Page Engineering and Dr. Kurt Hegmann, all of whom are well known from their robust “expert witness” practices
  - Given the curious background of your request and BMWED’s spurned outreach to AAR and other interested parties, we respectfully deny your request.
AAR consultants write Letters to the Editors of JOEM, AJIH, Industrial Health

- AAR consultants stated “several concerning scientific limitations.
  - “manuscript substantially misleads the readerships”
  - Study design
  - Subjective recall
  - Response rate
  - Selection bias
  - Validity of survey questions
  - Measures of exposure (self-reported)
  - Statistical methods (cross-sectional)
- “The authors report no conflicts of interest.”

Individual funding information (Letter to the Editor of JOEM):

This research has been funded in part by the Association for American Railroads.
This research has been approved by the Institutional Review Board of the University of Utah.

Dr Thiese has received funding from SafeLane Health, Union Pacific Railroad, and a partner-ship between Reed Group and the American College of Occupational and Environmental Medicine, and his institution has received funding from National Institute for Occupational Safety and Health, the Association of American Railroads, Utah State Bar, and a partnership between Abt and the Center for Disease Control and Prevention.

Dr Hegmann has received funding from SafeLane Health, Union Pacific Railroad, Burlington Northern Santa Fe Railway, Reed Group, and the American College of Occupational and Environmental Medicine (Practice Guidelines), and his institution has received funding from National Institute for Occupational Safety and Health, the Association of American Railroads, and a partnership between Abt and the Center for Disease Control and Prevention.

Mr Page has received funding from the Association of American Railroads and the primary railroads in the United States, including the Union Pacific Railroad and Burlington Northern Santa Fe Railway, to consult on ergonomics matters and provide expert testimony regarding ergonomics exposures in the workplace.

Mr Weames has received financial compensation from the Association of American Railroads and most all of the primary railroads in the United States and Canada, including Union Pacific, Burlington Northern Santa Fe, Canadian Pacific, Kansas City Southern, CSX, and Norfolk Southern to consult on ergonomics matters and provide expert testimony regarding ergonomics exposures in the workplace.

The authors report no conflicts of interest.
Authors Response(s) to the Letter(s) to the Editor

• Addressed criticism
• IRB and external international expert guidance
• Access to “raw data” controlled by the BMWED union
  ➢ To prevent possible misuse
  ➢ History of retaliation by railroad employers
• Railroad corporations/AAR denied any access to railroad work sites
  ➢ AAR consultants did not provide own data to support their assertions
  ➢ no peer reviewed studies
• Raised “conflict of interest” issue of AAR consultants
• BMWED offered research team reports to the AAR and railroad companies.
• BMWED invited AAR and US railroads to conduct a collaborative follow-up study.
• Researchers from NIOSH have offered technical assistance
Raising “Concerns” – a method to manufacture doubt or controversy -

• JOEM and AJIM – “CONFLICTS OF INTEREST” statement required
• Industrial Health – no CoI statement
• US Federal Employers Liability Act (FELA) – Publications = “notice to employers”
  • showing “negligence and proximate cause”
• Examples of Corporate challenge of studies and “manufactured” doubt:
  - Asbestos
  - Smoking
  - Lead
  - Pesticides
  - Climate change / Fossil fuels
• Daubert decision of the US Supreme Court (1993) – Judges become “gatekeeper” of science in courts
Recommendations – Ethical guidelines –

American College Occupational and Environment Medicine (ACOEM):

• primary responsibility to the health and safety of individual worker
• should behave honestly and ethically in all professional relationships
• **Obligation to Maintain Patient Confidentiality**
• **Obligation to Address Conflict of Interest**
  • conflict of interest is a prevalent condition, not a behavior
  • conflict exists … also if “might be perceived”
  • Ethical practice must ensure that harm does not accrue
  • CoI may be addressed with disclosure, informed waiver or disengagement

Recommendations – Ethical guidelines

ICOH – International Code of Ethics for occupational health professionals

• sound scientific basis with full professional independence
• …review of protocols and potential conflicts of interest by an independent and competent ethics committee and protection of confidential data
• The occupational health professionals have a duty to make their research results publicly available
• They are accountable for the accuracy of their reports

• David Michaels (former Assist. Secretary for Environment, Safety, and Health in the US Dep of Energy)

‘Doubt is their product: How industry’s assault on science threatens your health’ (2008)
• disclosure of special interests in the funding and publication of science
• better quality and independent health data re-analysis
• Congressional protection for industry whistleblowers and publicly funded scientists
Recommendations – Ethical guidelines

• P. Westerholm ‘Professional Ethics in Occupational Health -Western European Perspectives’ (2006)
  ➢ ICOH
  ➢ Guidance on Ethics for Occupational Physicians (Faculty of Occupational Medicine (FOM) of the Royal College of Physicians, London, UK (2018)
    o Data protection, whistleblowing, duty of candour
  ➢ International Code of Conduct (Ethics) for Occupational Safety and Health Professionals (Ladou et al. 2003, Occ Med)
    o promote ethical behavior, though compliance is voluntary and enforcement is generally not possible
    o same code of conduct apply to industrializing countries just as it applies to developed countries

• Association of Occupational and Environmental Clinics (AOEC), USA:
  ➢ Patient Bill of rights
  ➢ ICOH

• Faculty occupational Medicine (2017, UK):

“If you are in doubt about whether there is a conflict of interest, act as though there is..”